

REMARKS

In the Official Action dated December 14, 2001, claims 18-19 have been rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Claims 18 and 19 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Green et al. (The Veterinary Record, May 2, 1987; hereinafter "Green et al.") and Geresi et al. (1985) Ann. Immuno. Hung 25:37-40 hereinafter "Geresi et al." in view of Wu et al. (1992) J. Immunol. 148:1519-1525 and Gluck et al., U.S. Patent No. 5,879,685 (hereinafter "Gluck et al."). The Examiner has allegedly not received certain references cited in an Information Disclosure Statement, which was mailed on January 11, 2001. Copies of missing references have therefore been requested.

This response addresses each of the Examiner's rejections. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claims 18 and 19 have been rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. The Examiner alleges that the term "derived" in claim 18 is a relative term, thereby rendering the claim unclear and indefinite. In an effort to expedite favorable prosecution, Applicants have deleted the recitation "derived" from claim 18. Claim 18 has also been amended to further clarify the invention to which Applicants are entitled. Support for the amendment to claim 18 is found throughout the specification and particularly at page 4, lines 33-36, for example. No new matter has been added. Accordingly, the rejection of claims 18 and 19 under 35 U.S.C. §112, second paragraph is overcome and withdrawal thereof is respectfully requested.

Claims 18 and 19 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Green et al. and Geresi et al. in view of Wu et al. and Gluck et al.

The cited art does not provide any suggestion or motivation to make the claimed invention. There is no motivation, teaching or suggestion in the cited references to combine the separate features of Green et al., Geresi et al., Wu et al. and Gluck et al. Such combination does not arrive at the claimed invention in any event. The rejection of claimed subject matter as obvious under 35 U.S.C. §103(a) in view of a combination of cited references requires that the suggestion to carry out the claimed invention must be found in the cited art, not in Applicants disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991).

The Examiner alleges that Green et al. teach a formulation of a multivalent clostridial vaccine for the purpose of stimulating a protective immune response against multiple strains and species of Clostridia. The Examiner admits that Green et al. fail to teach a viral antigen.

Green et al. teach a vaccine composition, which includes an aluminum hydroxide adjuvant. Applicants submit that aluminum compounds are specifically described as being unsuitable adjuvants for vaccine compositions. Specifically, according to the present specification, aluminum compounds provoke severe, persistent local reactions, such as granulomas, abscesses and scarring, when injected subcutaneously or intramuscularly (see specification page 2, lines 1-7). Thus, Green et al. provide a clear teaching away from the composition of the present invention.

Geresi et al. teach a freeze-dried vaccine composition having *C. perfringens* antigens (C-D-type toxins) and another combined antigen. Notably, Geresi et al. teach that the combination of *C. perfringens* antigens “depressed the value of the immunity-degree developed after the introduction of the combined antigens”. Thus, Geresi et al. disclose that antigen competition results in a reduction in the immunity conferred by the vaccine. Such competition is purportedly mitigated only by the use of *Bordetella avium* (see page 40). However, Geresi et al.

report that a vaccine including *B. avium* "cannot be applied for preventing...infectious diseases". Furthermore, and as admitted by the Examiner, Geresi et al. fail to teach the use of an adjuvant, per se. Thus, Geresi et al., like Green et al. fail to suggest, no less motivate the preparation of a multicomponent vaccine composition including an antigen from a respiratory virus and a saponin adjuvant, as presently claimed.

The secondary references, Wu et al. and Gluck et al. fail to ameliorate the deficiencies of the primary references. Wu et al. disclose that a saponin adjuvant in association with a recombinant HIV envelope protein produced a higher titer of antibodies in test mice compared to controls vaccinated only with an alum-adsorbed HIV envelope protein. The Examiner acknowledges that Wu et al. do not teach a respiratory virus antigen.

Gluck et al. teach a method for obtaining an immunostimulating reconstituted influenza virosome (IRIV) containing an antigen such as a virus and bacteria such as *C. tetani*. Nowhere do Wu et al. or Gluck et al. disclose or suggest a multicomponent clostridial vaccine composition comprising a saponin adjuvant. It is therefore submitted that none of the references alone or in combination, teach or suggest a multicomponent clostridial vaccine composition comprising at least two species or serotypes of clostridium, an antigen from a respiratory virus and a saponin adjuvant.

In fact, the only suggestion to combine the separate elements of the cited references on this record is the Examiner's own view and the application of hindsight in the reconstruction of the cited art. There is simply no evidence of even the desire to achieve the claimed invention resident in the cited art of record.

In the present case, the Examiner has not met the burden of demonstrating either an explicit or implicit suggestion in the cited art to combine the separate features of Green et al., Geresi et al., Wu et al. or Gluck et al. in order to achieve the claimed invention. There must be


an indication in the cited art as a whole to suggest a desirability, and thus the obviousness of making the combination. In re Newell, 891 F.2d 899, 13 U.S.P.Q. 2d 1248 (Fed. Cir. 1991). There is no such suggestion identified on this record. Applicants respectfully submit that, at best, the combination of the cited references would have been "obvious to try"; a standard long-held not to constitute obviousness (see, In re O'Farrell 853 F.2d 894, 903 7 U.S.P.Q. 2d 1673, 1680-81 (Fed. Cir. 1988)). Thus, the rejection of claims 18-19 under 35 U.S.C. §103(a) is overcome and withdrawal thereof is respectfully requested.

The Examiner alleges that certain references listed in an Information Disclosure Statement mailed on January 11, 2001 were not located. Accordingly, Applicants provide herewith copies of the references requested by the Examiner to complete the file.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

Thus, in view of the foregoing amendments and remarks, the application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 18 has been amended as follows:

18.(Amended) A multicomponent clostridial vaccine composition comprising: (i) immunogens from at least two [or more] species or serotypes of Clostridium; (ii) an antigen [derived] from a respiratory virus; and (iii) a saponin adjuvant.